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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,435	09/06/2000	Akiko Itai	195832US	9728

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/14/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/656,435

Applicant(s)
Itai et al.

Examiner
Michael Borin

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 10, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/10/03 has been entered.

Status of Claims

1. Amendment filed is acknowledged. All previously pending claims, claims 6-11, are canceled. Claims 12, 13 are added. Claims 12, 13 are pending.

Claim Rejections - 35 USC § 112, second paragraph.

2. Claims 12,13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 12: The preamble recites that the objective of the method of the claim is to identify docking configuration of heteroatoms. It is not clear how configuration

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refers to heteroatoms, rather than to configuration of ligand (as addressed in the specification).

B. Claim 12: It is not clear, in the preamble, what is a configuration "in a ligand with biopolymer". Is configuration of the active conformation of ligand complexed with biopolymer is meant? Also, are heteroatoms recited in preamble belong to ligand or biopolymer?

C. Claim 12, preamble: The term "stable" in regard to "docking configuration of heteroatoms in a ligand with biopolymer" is not clear. The method steps are limited to matching distances between heteroatoms and dummy atoms, there are no steps to determine any "stability"; therefore, the meaning of this term (conformational, energetic, etc.) is not clear.

D. Claims 12,13, step A: Step A recites that three dimensional coordinates of certain conformation are entered. It is not clear which conformation: the conformation is being changed - see step C.

E. Claims 12,13, step B: It is not clear whether dummy atoms are placed in position of heteroatoms of ligand, of biopolymer, and/or both. If the dummy atoms are placed in the place of heteroatoms of the ligand, it is not clear what relation the claimed step have to biopolymer, and to ligand-biopolymer complex, as the method steps address manipulation with molecule of the ligand alone.

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F. Claims 12,13, step D. The steps involved in the "selecting" are not clear. From the claim language it seems that the heteroatoms are placed in their original position addressed in the first method step, step A, because, according to step B, dummy atoms are placed in position of heteroatoms, and, according to step D, in reverse, the heteroatoms are placed back in position of dummy atoms.

As addressed in previous Office actions, the term "selecting" remains vague and indefinite. Specification discussed selecting "possible" docking structures, but criteria for selection of such structures are not clear. In fact, the claims relate the dummy atoms (with the understanding that they are derived from ligand) with the ligand itself, not the biopolymer. There is no nexus to biopolymer-ligand interaction.

G. Claim 13: It is not clear, in the preamble, what is a conformation of "a ligand with biopolymer". Is conformation of "biopolymer-ligand molecule complex" (i.e., as in the title of the invention) meant?

H. Claim 13, preamble: The term "active" in regard to "conformation of a ligand with a biopolymer" is not clear. The method steps are limited to matching distances between heteroatoms and dummy atoms, there are no steps to determine any "activity". There is no nexus to activity of biopolymer or ligand and/or biopolymer-ligand interaction. Therefore, the meaning of this term is not clear.

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Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12,13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The new claims 12,13 are drawn to methods wherein the heteroatoms, after performing method steps, are positioned in their original position - note that it seems that the heteroatoms are placed in their original position addressed in the first method step, step A, because, according to step B, dummy atoms are placed in position of heteroatoms, and, according to step D, in reverse, the heteroatoms are placed back in position of dummy atoms. The specification, in contrary, addresses methods comprising evaluating hydrogen bond schemes in ligand-biopolymer interactions.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321[©] may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

4. Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of US Patent 6,308,145 or claims 1-6 of US patent 5,642,292. The claims of the parent applications recite methods which comprise method steps as instantly claimed. Claim 1 of US Patent 6,308,145 and claims claim 2 of US patent 5,642,292 are shown as examples.

US 6,308,345:

1. A method which comprises:

inputting three-dimensional coordinates for each atom of a biopolymer as well as atomic element, bond-type of covalent bonds and three-dimensional coordinates for each atom of a ligand;

covering all possible docking structures between said biopolymer and said ligand while changing the conformation of said ligand; and

outputting information about three-dimensional coordinates for each atom of the ligand in one or more stable docking structures including the most stable docking structure relative to the biopolymer, the stability of said docking structures, as well as the binding modes and conformations of the ligand in said structures, wherein possible binding modes between the biopolymer and the ligand are covered by examining all combinations of correspondences between dummy atoms and heteroatoms in the ligand instead of changing relative positions and orientations between the two molecules, said dummy atoms

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being preset at the positions of heteroatoms that can be hydrogen-bonded with the hydrogen bonding groups in the biopolymer.

US 5,642,292:

2. A method which comprises:

preparing exhaustive combinational sets of the correspondences between dummy atoms and the hydrogen-bonding atoms in a ligand, said dummy atoms being preset on the positions of heteroatoms that can be partners to the hydrogen-bonding of the hydrogen-bonding functional groups in a biopolymer, comparing, for each correspondence, the distances between the dummy atoms with the distances between the corresponding hydrogen-bonding heteroatoms in the ligand with the conformation of the ligand being changed regularly, thereby selecting combinations of favorable correspondences between the dummy atoms and the heteroatoms with conformations of the ligand,

generating the possible structures of the complex by fitting said ligand into the coordinate system of said biopolymer on the basis of said favorable correspondences, and

estimating the possible schemes of binding between the biopolymer and a hydrogen-bonding part of the ligand simultaneously with the possible conformations of said hydrogen-bonding part.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

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Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 11, 2003

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

